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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Lanfranco Callegaro

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/743,333	<b>Applicant(s)</b> CALLEGARO ET AL.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-32 and 34-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-32 and 34-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, declaration under 37 CFR 1.132, amendment and remarks, all filed 04/01/2009. Claims 25, 34 and 39-44 are amended. New claims 45-51 are added. Claims 25-32 and 34-51 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/01/09 has been entered.

#### ***Response to Arguments***

**Previous rejections that are not reiterated herein are withdrawn.**

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 25-32 and 34-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

5. The amended claims have recited seeding and growing enterocytes. But the specification as filed does not envision seeding enterocytes. Applicant indicates that the amendment is supported by the specification as filed. The examiner does not find support for seeding enterocytes. Rather, page 6 of the specification states at lines 7 and 8 that calcium carbonate cells derived from human colon carcinoma differentiates into enterocytes of the mature intestinal epithelium.

6. Applicant may overcome the rejection by removing the new matter.

7. Claims 25-32 and 34-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The boundaries for the protection sought for derivatives of hyaluroniuic acid as recited in the claims are not discernible making the scope of the claims unclear and indefinite

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **The claim amendment:** The claims have been amended to specifically recite seeding and growing enterocytes on bidimensional perforated membrane or on bidimensional continuous membrane .... Enterocytes are epithelial cells found in the intestines and in the colon. The matrix upon which the intestinal cells are seeded for growing is porous bi-dimensional or continuous bidimensional membrane that consists essentially of at least one hyaluronic acid or derivative. The recitation of morphologically differentiated intestinal cells is a consequence of the natural development within the intestinal cells; and the artisan has the technical capabilities to determine absence of presence of microvilli, which would inherently be present in intestinal cells undergoing morphological differentiation.

12. Claims 25-32 and 34-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 5,939,323).

In column 1, lines 64-67, Valentini describes that derivatives of hyaluronic acid are employed as raw materials to fabricate porous, degradable scaffolds for medical purposes such as tissue repair and reconstruction and wound healing. In column 2, lines 7-22, Valentini goes on to say that the porous scaffold can be fabricated to any size and shape, produced to virtually any

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desired predetermined pore size depending on the application. However, the resulting scaffold of Valentini is “three dimensional biodegradable scaffolds of hyaluronic acid derivatives for tissue reconstruction and repair,” (column 4, lines 31-33) using the derivatives of HA, such as HYAFF (see Examples 1-3, 5 for the use of the HYAFF) as raw material to fabricate porous, degradable scaffolds for tissue repair and wound healing (See column 1, lines 64-67); and specifically discloses that the scaffolds can have virtually any size, thickness and shape having various porosities and pore sizes (column 4, lines 36-38) and which can be used for attachment of bioactive molecules (See column 2, lines 7-22). For Valentini, the most preferred hyaluronic acid derivative is hyaluronic acid esterified with a benzyl moiety (See column 2, lines 54-67) meeting claims 27-32 and 35-37. Valentini discloses that the scaffolds may be used for repair of bone defects, for treating non-healing fractures and osteoporetic lesions, for treating tooth and jaw defects and cartilage defects, for repair of defects and damage in skin, muscle and other soft tissues (column 7, lines 36-57 and column 8, line 1) and that in each of these cases, the scaffold is seeded with cells that would differentiate into the respective damaged tissues ((column 7, lines 36-57 and column 8, line 1). Valentini also discloses that “likewise, damage to visceral organs including liver damage, ... damage resulting from intestinal cancer or intestinal ulcer may be treated with the scaffolds of the invention. In these instances, the scaffolds can be seeded with cells such as ... intestinal cells,” (column 8, lines 1-6). The perforated membrane of the claims read on the porous scaffold of Valentini, which scaffold can also be a membrane. Because the enterocytes are epithelial cells found in the small intestine or colon, it flows that seeding intestinal cells on the hyaluronic acid matrix may also represent seeding enterocytes on the

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hyaluroniu acid matrix so that seeding enterocytes in claim 25 and materials of claims 34, 39-51 that comprise enterocytes are met.

Claims 34 and 39-51 are product by process claims and the requirement for fibroblasts, mesenchymal cells, mature cells and/or epithelial in the biological material is optional. However, Valentini specifically notes that the scaffold may be/is seeded with precursor cells, for example, mesenchymal stem cells from bone marrow, periosteum, endosteum, etc, which are bone cell precursors, are seeded onto the scaffold in the case of bone repair where (column 7, lines 39-43). Furthermore, "morphological differentiation of intestinal cells" now recited in the amended claim 25 appears to be natural development within the seeded cells so that the intestinal cells seeded by Valentini on the scaffold must undergo the "morphological differentiation." Nonetheless, Valentini clearly recognizes and discloses that cells seeded onto the scaffold differentiate into the respective tissues as is described in column 2, lines 10-12 and 22; column 3, lines 15, 58; column 4, line 9; column 6, lines 31-38; column 8, line 10; column 10, lines 5, 64 and 65; and column 11, line 30.

Thus, Valentini provides HA matrices for the ingrowths of intestinal cells. One skilled in the art would understand the scaffold of Valentini to be single layer and porous or perforated membrane. Valentini does not describe a 2-D matrix as now recited in the claims. But, while Valentini uses 3-D scaffold, Valentini also indicates that the scaffold can be fabricated to any size and shape, produced to virtually any desired predetermined pore size depending on the application (column 2, lines 7-22). Therefore, taking the general teaching of Valentini as regards the design and use of scaffold of any shape and structure and size, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success

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that intestinal cells seeded on the 3-D matrix or any other structural matrix including a 2-D matrix or continuous matrix will grow. The prior art and the claimed invention achieve the same result of growing intestinal cells by seeding intestinal cells on hyaluronic acid matrix. There is no demonstration that intestinal cells cannot be seeded on the 3-D matrix of Valentini.

***Response to Arguments***

13. Applicant's arguments filed 04/01/09 have been fully considered but they are not persuasive.

14. a) Applicant argues that Valentini does not describe a 2-D material matrix, that the examiner arbitrarily isolated sentences from Valentini in order to "conveniently lead to claimed invention" by hindsight reconstruction of the claimed invention; that Valentini expressly and unambiguously refers to a three dimensional scaffold when Valentini suggests that "virtually any size, thickness and shape having various porosity and pore size" can be used.

15. The examiner agrees with applicant that Valentini teaches 3-D matrix as was stated in the rejections and that is the reason for the rejections under 35 USC 103. However, there is no arbitrary reconstruction to arrive at the claimed invention. Valentini's suggestion for use of any shape or size matrix does not limit the shape to a 3-D matrix because 3-D and 2-D and uni-D are all geometrical variations that an object may assume. Applicant excludes uni-D and 2-D from Valentini's without a convincing argument as to why the variation suggested must be limited to a 3-D while the scaffold of Valentini can also be membrane. Thus, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only



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knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In the present case, Valentini suggests that the scaffold can be a membrane scaffold and a suggestion that any shape and size can be used. Placing the scaffold in a membrane insert (see paragraph 3, titled "BMP Release Bioassay by Alkaline Phosphatase (AP) Induction of Pluripotent Stem Cells" suggests that the scaffold that fits into the membrane insert would be membrane-like to fit the membrane insert and the section under paragraph 3, titled BMP Release Bioassay by Alkaline Phosphatase (AP) Induction of Pluripotent Stem Cells" is the section that suggest membrane structure for the scaffold of Valentini and provides response to applicant's inquiry as to where the suggestion for membrane would be found. Further it is noted that applicant has picked sections of Valentini to support applicant's insistence that the scaffold of Valentini must be 3-D and ascribes 3-D only to the Valentini's suggestion that virtually any size, shape, thickness and a structure that can be used to attach bioactive molecules.

16. Applicant argues that the expectation of success falls flat when the teaching of Valentini is not followed. The examiner respectfully disagrees with the applicant because the rejection does not advocate that one should not follow the teaching of Valentini. Rather, modifications of prior art teachings within the guidelines of 35 USC 103 is permitted when expectation of success is high, which in this case is the growing of intestinal cells that inherently contain enterocytes. Valentini grows intestinal cells or cells. Cells are grown also on the claimed matrix so that it is reasonable to expect and iterate that, both the claimed invention and the Valentini work grows cells on hyaluroniu acid matrices. Thus expectation of success does not fall flat.

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17. Applicant disagrees that intestinal cells seeded in hyaluronic matrix would undergo morphological differentiation and presents declaration that says differentiation of intestinal cells cannot take place in hyaluronic acid matrix. However, it is noted that the declaration uses compositions that are different from that which is claimed and as such not commensurate with the claims. The declaration is addressed below.

18. Declaration under 37 CFR 1.132 by Anna Zanellato:

19. The declaration under 37 CFR 1.132 filed 04/01/09 is insufficient to overcome the rejection of claims 25-32 and 34-51 based upon the rejections under 35 USC 103 over Valentini et al. (US 5,939,323) as set forth in the last Office action because: The declaration uses specific cells derived from CaCO<sub>3</sub> cell lines and not any enterocytes as claimed. The specification also uses specific concentrations and the claims have not. Thus, the declaration is not commensurate with the claims.

20. Claims 25-32 and 34-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorigatti et al. (WO 94/17837) in view of Valentini et al. (U.S. Patent 5,939,323).

Dorigatti provides a multilayer non-woven material comprising *a layer* coming in contact with the skin and that layer is made of materials selected from the group consisting of a derivative of hyaluronic acid, specifically a hyaluronic acid ester, and a perforated membrane compatible with cell growth on its surface (See p. 2, lines 16-34) with the layer comprising the hyaluronic acid derivative meeting a single layer in which cells are seeded because it is the *perforated layer that is in contact with the skin* (page 6, lines 14-21). Dorigatti teaches that the perforated membrane may include glycosaminoglycans (See p. 6, lines 13-29) and the non-

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woven tissue can be impregnated with pharmaceutically active compounds and be used in surgery because of its anti-adhesive properties (See p. 7, lines 16-28). The derivatives of hyaluronic acid is HYAFF (see Examples 1-7), which is the same hyaluronic acid derivative of the invention as gleaned from applicant's specification at page 6, line 26 and page 7, line 7, meeting claims 26-32 and 35-38. Claims 34 and 39-51 are product by process claims and the presence of cells other than the intestinal cells is optional.

Thus, with regard to claims 25, 34 and 39-44, the international publication provides the general teachings that cells can be grown on a single layer of hyaluronic acid esters and/or a perforated membrane comprising glycosaminoglycans and hyaluronic acid derivative. The material may be used in surgeries, where its anti-adhesive properties are required. Dorigatti is deficient in the sense, that the publication does not specify the type of cells, which may be grown on hyaluronic acid containing perforated membrane that is in contact with the skin or Dorigatti contemplates growing a variety of cells on hyaluronic acid containing perforated membrane that is in contact with the skin.

With respect to claims 26-32 and 35-38, Dorigatti teaches that hyaluronic acid esters are preferred in the layer contacting the skin (See p. 2, lines 30-34), and includes the esters of hyaluronic acid disclosed in U.S. 4,851,521 and comprising esters of hyaluronic acid with alcohols, sulfonic acids and neutral sulfates, among the hyaluronic acid esters used in the invention (See p. 4, lines 26-29). Furthermore, "morphological differentiation of intestinal cells" now recited in the amended claim 25 appears to be natural development within the seeded cells so that the cells seeded by Dorigatti on the perforated layer comprised of HYAFF must undergo the "morphological differentiation."

But, Valentini discloses seeding or growing intestinal cells on HYAFF (column 7, line 36 to column 8, line 17) and thus provides the deficiency of Dorigatti. Enterocytes are epithelial cells found in the intestines and in the colon so that the intestinal cells intrinsically contain enterocytes.

Therefore, a person of ordinary skill in the art, taking the references together would grow intestinal cells (that intrinsically contains enterocytes) or any other cells on the perforated membrane layer of Dorigatti since Valentini discloses that intestinal cells can grow and differentiate on HYAFF matrices. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

#### ***Response to Arguments***

21. Applicant's arguments filed 4/01/09 have been fully considered but they are not persuasive.

22. Applicant argues that Dorigatti does not disclose intestinal cells. The examiner agrees and that is why the rejection was made under 35 USC 103. Dorigatti is different in the sense that no specific cells were identified and Valentini was used to show that intestinal cells that inherently contain enterocytes are seeded on hyaluronic acid matrix. Applicant appears to be arguing against the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the present case, the combination of Dorigatti and Valentini was used to show that the claimed invention is obvious.

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23. Applicant argues that Dorigatti and Valentini are not in the same field of endeavor. But, Dorigatti teaches growing cells on hyaluronic acid membrane and Valentini grows specific cells in hyaluronic acid matrix. The goals are congruent, that is, growing cells on saccharide matrix.

24. Applicant argues that prima facie case of obviousness was not established. The examiner disagrees. Prima facie case of obviousness was established because Dorigatti grows any cells on hyaluronic acid matrix, Valentini grows intestinal cells on hyaluronic acid matrix. It is prima facie to expect that the intestinal cells of Valentini would be successfully seeded and grown in the hyaluronic acid matrix of Dorigatti. Valentini provides a teaching that intestinal cells can be seeded on hyaluronic acid matrix or that hyaluronic acid matrices support growth of intestinal cells. By focusing on Dorigatti when the rejection was over two references, applicant is arguing against the references individually, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

25. Applicant further argues that the examiner has used hindsight reasoning to arrive at the claimed invention. The examiner disagrees. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the present case, Dorigatti

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teaches growing any cells on hyaluronic acid membrane. Valentini grow specific cells on hyaluronic acid matrix. Thus the specific cells which grow on the Valentini matrix would also grow on the hyaluronic acid membrane of Dorigatti. Membranes can take any geometric form and in fact a membrane cannot be 0-dimensional. Membranes can be bi-dimensional or tri-dimensional.

26. Claims 25-32 and 34-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soranzo et al. (WO 96/35750) in view of Valentini et al. (US 5,939,323).

Soranzo discloses perforated membrane based on hyaluronic acid derivative for growing seeded keratinocytes (abstract). Claims 26-32 recite different derivatives of hyaluronic acid and the generic disclosure for hyaluronic acid derivative encompasses derivatives of hyaluronic acid so that any derivative of hyaluronic acid can be used meeting claims 26-32. Many types of membranes are mentioned and LASERSKIN is specifically named (page 10, line 15) meeting the requirement for bi-dimensional perforated membrane as in claims 25, 34 and 39-51. Note that gleaned from applicant's specification at page 3, line 25 and declaration under 37 CFR 1.132 by Anna Zanellato, show that LASERSKIN is bi-dimensional perforated structure. Claims 34 and 39-51 are product by process claims and the requirement for fibroblasts, mesenchymal cells, mature cells and/or epithelial in the biological material is optional. Furthermore, "morphological differentiation of intestinal cells" recited in the amended claim 25 appears to be natural development within the seeded cells. Enterocytes are epithelial cells found in the intestines and in the colon.

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Soranzo does not seed intestinal cells. But, Valentini discloses seeding or growing intestinal cells on hyaluronic acid matrix/membrane (column 7, line 36 to column 8, line 17) according to the description above. Valentini also discloses that the scaffolds may be used to repair bone defects, for treating non-healing fractures and osteoporectic lesions, for treating tooth and jaw defects and cartilage defects, for repair of defects and damage in skin, muscle and other soft tissues (column 7, lines 36-57 and column 8, line 1) and that in each of these cases, the scaffold is seeded with cells that would differentiate into the respective damaged tissues ((column 7, lines 36-57 and column 8, line 1). Thus Valentini cures the deficiency of Soranzo so that the intestinal cells seeded by Valentini on the scaffold must undergo the “morphological differentiation.” Nonetheless, Valentini clearly recognizes and discloses that cells seeded onto the scaffold differentiate into the respective tissues as is described in column 2, lines 10-12 and 22; column 3, lines 15, 58; column 4, line 9; column 6, lines 31-38; column 8, line 10; column 10, lines 5, 64 and 65; and column 11, line 30. Therefore, taking the teachings of the references together, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that intestinal cells seeded on the hyaluronic acid membrane of Soranzo would grow and differentiate. Since enterocytes are epithelial cells found in the intestines and in the colon, the intestinal cells inherently contains enterocytes.

### ***Response to Arguments***

27. Applicant's arguments filed 4/01/09 have been fully considered but they are not persuasive.

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28. Applicant argues that Valentini and Soranzo are not in the same field of endeavor of the claimed invention. The examiner disagrees because Valentini, Soranzo and the claims are all concerned with growing cells on saccharide matrix and thus appear to have congruent goals.

29. Applicant argues that both Soranzo and Valentini describe 3-D matrices/structure. This argument is not persuasive. Soranzo uses LASERSKIN, which is a 2-D perforated structure.

Valentino suggests that the scaffold could assume the structure of a membrane because Valentino places the scaffold in a membrane insert (see paragraph 3, titled “BMP Release Bioassay by Alkaline Phosphatase (AP) Induction of Pluripotent Stem Cells” which is suggestive that the scaffold that fits into the membrane insert would be membrane-like to fit the membrane insert and the section under paragraph 3, titled BMP Release Bioassay by Alkaline Phosphatase (AP) Induction of Pluripotent Stem Cells” is the section that suggest membrane structure for the scaffold of Valentini and provides response to applicant’s inquiry as to where the suggestion for membrane would be found. There is thus no hindsight reconstruction from Soranzo that teaches 2-D perforated LASERSKIN.

30. **Duplicate Claims:**

31. Applicant is advised that should claims 34, 39-44 be found allowable, claims 45-51 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

32.

No claim is allowed.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/  
Examiner, Art Unit 1618